Protecting Patients on the Factory Floor: Why Pharmacists should supervise Drug Production

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Clause 31 of the recently passed National Drug and Health Products Authority bill 2025 provides that:

> "A person licensed to manufacture a drug in Uganda shall manufacture the drug under the direct supervision of a pharmacist"

Following the passing of the bill, there are some reports stating that there are some individuals within the scientific community who claim that this clause 31 of the bill has excluded other scientists in drug manufacturing. This is not only untrue but misleading. Clause 31 speaks to industrial pharmacy practice. This is a core domain of pharmacy practice as defined by the World Health Organisation(WHO) and the International Pharmaceutical Federation (FIP). The joint FIP/WHO good pharmacy practice guidelines define pharmacists' first major role to be the stewardship of medical products including but not limited to preparing (manufacturing), obtaining, storing, securing, distributing, administering, dispensing and disposing of them. In the same global professional architecture, FIP's Board of Pharmaceutical Practice explicitly lists industrial pharmacy as one of its pharmacy practice sections, and FIP's Industrial Pharmacy Section describes itself as covering all functions where industrial pharmacists work and focusing on the development of safe, effective, high-quality and affordable medicines. Taken together, those WHO-linked and FIP sources place industrial pharmacy unambiguously as a professional practice for pharmacists. Furthermore, colleagues mobilizing support against the bill are passionately quoting some guidelines without appreciating that these guidelines have caps and the cap in all these guidelines is national legislation. Every country has to be intentional.

In Uganda's case, the Parliament considered Africa's leading pharmaceutical markets—Egypt, South Africa, and Nigeria—and benchmarked their regulatory frameworks for the professional responsible for supervising pharmaceutical manufacturing, since they are all ML3 Countries. In all three jurisdictions, a pharmacist is designated as the regulated professional overseeing the manufacture of medicines.

Pharmacists possess integrated clinical and scientific training in medicines, equipping them with a distinctive combination of skills, knowledge, and professional judgment required for this role.

The pharmacists' practice is also strongly grounded in statutory regulation, reflecting established best practice in safeguarding public health. This requirement does not exclude the contributions of other professionals, including scientists and engineers, who play critical roles across the pharmaceutical value chain. Rather, pharmacist oversight ensures that innovation is conducted responsibly, with patient safety and therapeutic outcomes at the forefront.

Uganda's pharmaceutical sector continues to expand, supported in part by the existing legal requirement for pharmacist supervision. Notably, assessments by the World Health Organization of manufacturing licensing functions have not identified this requirement as a deficiency, further reinforcing its alignment with good regulatory practice.

Industrial Pharmacy is therefore a regulated aspect of practice and as provided under Section 22 of the Pharmacy and Drugs Act Cap 309 Laws of Uganda (Revised laws 2023 Edition), the Council of the Pharmaceutical Society of Uganda (PSU) is mandated to prescribe the highest practicable standards of pharmacy practice in Uganda, which is done in a bid to protect the public. PSU Council is in support of clause 31 in the way it has been passed. The positioning of industrial pharmacy practice as a recognised pharmacy practice domain remains critical to public health and while pharmacists work with other professionals and pure scientists including engineers, analytical chemists, and medicinal chemists among others, the professional duty to ensure the public is protected from release of poor-quality medicines lies with the pharmacist, as a regulated professional. This is a prerequisite to protect public health and in no way does it preclude or exclude the recognised contribution of applicable graduates.

To prepare pharmacists for this critical task, several countries including across Africa and Europe, provide for enhanced* duration of intense study of pharmacy in a structured manner covering the convergence of the science of medicines and patient safety. This study, covering both theoretical and practical elements covers a period of not less than Five (5) years including government regulated internship and in some countries goes up to 6 years. This duration is not in error. It is expected that over this time, a professional is developing and armed to protect and preserve patient safety. For instance, Directive 2005/36/EC requires pharmacist training to include knowledge of medicines and of the substances used in their manufacture, pharmaceutical technology, and the physical, chemical, biological and microbiological testing of medicinal products. The same Directive then provides that holders of pharmacy qualifications must be able to access at least the activities of preparing the pharmaceutical form of medicines, manufacturing and testing medicinal products, laboratory testing of medicines, and wholesale-stage storage and distribution. That is a direct legislative statement that manufacturing and testing are within the professional sphere of pharmacy. In Uganda, these requirements have been incorporated in the minimum standards for Bachelor of Pharmacy curriculum.

The law prescribing pharmacist led supervision of drug production is paramount for public-protection since in Uganda, like other countries, pharmacy is a regulated profession. A regulated profession is one whose access or pursuit is legally tied to specific professional qualifications and government control including the possibility of dire professional consequences in case of misconduct or endangering public health. Specifically, government pharmacist regulation adds protected title, mandatory education and training standards, licensing, reserved activities, continuing oversight, and the possibility of disciplinary intervention. Like in Uganda, in countries like the UK, pharmacists are described as medicines experts whose expertise covers both the science and patient care. Upon this, there are reserved supervisory activities such as direct supervision of drugs and responsibility for supervising the supply and preparation of medicines. The advantage of a regulated profession is therefore not symbolic; it creates an enforceable chain of competence and accountability before harm occurs and after failures occur.

The above aspects explain why the supervision of drug manufacture should be entrusted to the pharmacy profession. A manufacturing supervisor must understand not only the science of medicine, its chemistry or microbiology in isolation, but the whole medicinal product as a therapeutic article in the context of patient care and clinical use. WHO warns that substandard medicines often arise from poor manufacturing practices or inadequate quality control, and that such products may contain wrong ingredients, wrong dosages, contaminants or toxic substances; WHO also estimates that at least one in ten medicines in low- and middle-income countries are substandard or falsified. A profession trained specifically in medicines across their development, manufacture, testing, legal control and patient use is therefore the most rational place to vest supervisory authority. Scientists from other disciplines remain indispensable members of the manufacturing team, but the supervisory function should sit with the profession whose curriculum is expressly designed around medicines with direct training in patient and pharmaceutical care.

There is also judicial support for this public-protection logic. In Commission v Italy and Apothekerkammer des Saarlandes, the European Union Court of Justice held that Member States can restrict pharmacy ownership and operation to pharmacists because medicines are of a very particular nature, incorrect or unnecessary use can seriously harm health, pharmacists' training, professional experience and responsibility exceed purely economic incentives, and non-pharmacists do not provide equivalent safeguards. The court's reasoning is highly persuasive by analogy to drug manufacturing: if pharmacist control can be justified at the final point of supply because medicines are risky and public health must prevail, the argument is even stronger at the manufacturing stage, where a single supervisory failure may compromise thousands or millions of dosage units before they ever reach a patient.

Uganda took note of this and left no room for ambiguity demonstrating the NRM's government commitment and uncompromised commitment to protecting Ugandans from unsafe medicines. This is why in the current law, supervision of the manufacture of medicines in unambiguously domiciled under the pharmacist. In so doing the Government went for the best possible practices. Uganda has now become a hub for pharmaceutical manufacturing as the number of pharmacists to supervise these operations have dramatically increased over the last years due to the establishment of several pharmacy training schools including Makerere University, Mbarara University of Science and Technology, Gulu University, Busitema University, Kampala International University, Victoria University , Finns medical University, Seeta University and Jeff International University. This provides direct highly skilled labour for the booming pharmaceutical industrial sector. More so, this is further supported by other scientists including engineers, chemical engineers, analytical scientists, biochemists among others. The requirement for pharmacy supervision does not preclude these scientists but rather guides their activities to ensure patients remain protected.

Accordingly, Industrial pharmacy practice is a well recognised pharmacy practice domain in global professional standards. Pharmaceutical manufacturing is a quality-and-safety system governed by GMP and pharmaceutical law; and the regulated pharmacy profession supplies the education, licensure, accountability and public-interest discipline best suited to supervise that system. On that basis, placing manufacture under pharmacist supervision is not guild protection or professional protectionism. It is the clearest way to protect the public from poor-quality, unsafe and ineffective medicines while preserving traceable professional responsibility for one of the highest-risk functions in the medicines supply chains.

Per medicatum servium
(With medicines, We serve)

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